FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1901-1950

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, Acting Administrator, Federal Security Agency.

WASHINGTON, D. C., February 20, 1947.

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DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

- 1901. Misbranding of Seconal Sodium Pulvules. U. S. v. V. R. Canalez (Ramona Drug Co.) and Garfield Gray. Pleas of guilty. Fine of \$200 imposed on V. R. Canalez; imposition of sentence suspended on remaining counts with respect to defendant Canalez and on all counts with respect to defendant Gray. Both defendants placed on probation for 1 year. (F. D. C. No. 20119. Sample Nos. 31175-H, 31176-H, 32227-H, 32245-H.)
- INFORMATION FILED: On or about April 29, 1946, District of Arizona, against V. R. Canalez, trading as the Ramona Drug Co., Phoenix, Ariz., and Garfield Gray, an employee of the Ramona Drug Co.
- ALLEGED SHIPMENT: Between the approximate dates of May 3 and August 6, 1945, from Indianapolis, Ind.
- LABEL, IN PART: "Pulvules Seconal Sodium 1½ grs. (0.1 Gm.) (Sodium Propylmethyl-carbinyl Allyl Barbiturate, Lilly) Warning—May be habit forming * * * Caution—To be dispensed only by or on the prescription of a physician."
- NATURE OF CHARGE: On or about July 31, 1945, while a number of capsules of the drug were held for sale after shipment in interstate commerce, the defendants removed 24 capsules from the bottle in which they had been shipped, repacked them in an unlabeled cardboard box, and sold them without a

^{*}For omission of, or unsatisfactory, ingredients statements, see Nos. 1909, 1923, 1928, 1939; failure to bear an accurate statement of the quantity of the contents, Nos. 1904, 1909, 1948; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 1909; failure to state quantity or proportion of narcotic or hypnotic substance, No. 1920; failure to comply with the packaging requirements of an official compendium, No. 1925; labeling information not likely to be understood by the ordinary individual, No. 1938.

prescription. On August 24 and September 18, 1945, the defendants removed from the bottle 24 capsules and 12 capsules, respectively, and sold them in

unlabeled boxes without a prescription.

The acts of the defendants resulted in the misbranding of the drug in the following respects: Section 502 (f) (1), the labeling on the box failed to bear any directions for use; and, Section 502 (f) (2), the labeling failed to bear adequate warnings against use of the drug in those pathological conditions wherein its use may be dangerous to health and against unsafe dosage and methods and duration of administration.

Disposition: May 15, 1946. Pleas of guilty having been entered, the defendant Canalez was fined \$200. Imposition of sentence was suspended with respect to defendant Canalez on the remaining counts and with respect to defendant Gray on all counts, and both defendants were placed on probation for 1 year.

1902. Misbranding of Seconal Sodium Pulvules. U. S. v. Ben Glina (Glina's Drug Store). Plea of nolo contendere. Fine, \$200. (F. D. C. No. 17849. Sample No. 31861-H.)

INFORMATION FILED: March 19, 1946, District of Arizona, against Ben Glina, trading as Glina's Drug Store, at Phoenix, Ariz.

INTERSTATE SHIPMENT: Between the approximate dates of July 21 and November 15, 1944, from Indianapolis, Ind.

Label, in Part: "Pulvules Seconal Sodium 11/2 Grains (0.1 Gm.) (Sodium Propyl-methyl-carbinyl Allyl Barbiturate, Lilly) Caution—To be used only by or on the prescription of a physician."

NATURE OF CHARGE: That on or about May 10, 1945, while the drug was being held for sale after shipment in interstate commerce, the defendant removed a number of the capsules from the bottle in which they were shipped, repacked a number of them into an unlabeled envelope, and sold them without a prescription.

The information charged further that the acts of the defendant resulted in the misbranding of the drug in the following respects: Section 502 (f) (1), the envelope containing the capsules bore no labeling containing directions for use; and, Section 502 (f) (2), the envelope bore no labeling containing warnings against use of the drug in those pathological conditions wherein its use may be dangerous to health and against unsafe dosage and methods and duration of administration.

DISPOSITION: May 13, 1946. A plea of nolo contendere having been entered, the court imposed a fine of \$200.

1903. Misbranding of benzedrine sulfate tablets. U. S. v. Louis L. Patt (Courtesy Drug Store) and Louis Spiegel. Pleas of nolo contendere. Fine of \$200 against Louis L. Patt; imposition of sentence against Louis Spiegel suspended for 1 year. (F. D. C. No. 20117. Sample No. 32225-H.)

INFORMATION FILED: April 24, 1946, District of Arizona, against Louis L. Patt, trading as the Courtesy Drug Store, at Phoenix, Ariz., and Louis Spiegel, an employee.

INTERSTATE SHIPMENT: Between the approximate dates of June 5 and July 3. 1945, from Philadelphia, Pa., of 1 bottle containing 250 benzedrine sulfate tablets.

Product: The drug had been made for use exclusively by or on the prescription of physicians, and its label bore the statement, "Caution: To be used only by or on the prescription of a physician." As a result, it was not required to comply with Section 502 (f) (1), which requires that adequate directions for use appear in the labeling.

Label, IN Part: "10 mg. Benzedrine Sulfate Tablets."

NATURE OF CHARGE: On or about July 27, 1945, while 11 tablets of the drug were being held for sale after shipment in interstate commerce, the defendants caused them to be sold, delivering them to the purchaser in the bottle labeled as indicated above, without a physician's prescription. The sale of the tablets by the defendant caused the exemption to expire and resulted in the misbranding of the drug in violation of Section 502 (f) (1), since the drug bore no labeling containing directions for use.

DISPOSITION: May 13, 1946. Pleas of nole contendere having been entered, the court imposed a fine of \$200 against Louis L. Patt. Imposition of sentence against Louis Spiegel was suspended for 1 year, and he was placed on proba-

tion for a like period.